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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,899	04/27/2007	Jean-Charles Schwartz	P08977US00/BAS	8912

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
07/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,899	SCHWARTZ ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *14-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment filed April 2, 2009 is acknowledged. Claims 1-19 are pending.

A Declaration under Rule 132, filed April 2, 2009, by Dr. Jeanne-Marie Lecomte is further acknowledged.

Newly submitted claims 14-19 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: As clearly set forth on page 2, second paragraph, in the Office Action mailed December 2, 2008, all original claims were drawn to the combination of an anti-emetic agent with an enkephalinase inhibitor and are pharmaceutical composition claims.

Since Applicants have received an Action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 14-19, directed to methods of treating acute gastroenteritis and methods of treating acute diarrhea associated with emesis, are withdrawn from consideration as being directed to a non-elected invention. Additional search and consideration of these method claims are required. See 37 CFR 1.142(b) and MPEP § 821.03.

Co-pending applications for the present inventive entity, i.e., S.N. 12/303,981 and S. N. 12/300,465, are noted.

Those rejections presented in the last Office Action that are not herein reiterated are withdrawn. The following rejections are the only rejections presently applied to the instant claims.

In the last Office Action claims 9-12 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because factors such as modes of administration, body weight, dosage forms, and renal and hepatic status, must be considered when formulating a dosage form. It was asserted the metes and bounds of the recitation "corresponding doses according to body weight for children and babies" in claims 9-12 cannot be precisely determined.

Applicants argue that on page 10 of the specification, any of the presently disclosed "compositions can be prepared in unit dosage form by any of the methods well known in the art of pharmacy." Applicants urge one of ordinary skill in the art would readily be apprised of the metes and bounds of the recitation "corresponding doses according to body weight for children and babies" in claims 9-12.

Applicants' argument is not found persuasive. The claims under consideration are pharmaceutical compositions. As such, they are finite formulations. Those factors that determine "corresponding doses according to body weight for children and babies" are indefinite. Accordingly, the rejection of record of claims 9-12 under 35 U.S.C. 112, second paragraph, is maintained.

Claims 1-19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Stroppolo et al., US 2004/0115258, in view of Boige et al., Bulletin du Cancer, in the last Office Action. It was asserted Stroppolo teaches pharmaceutical compositions in which "a plurality of active ingredients" may be blended with cyclodextrin in a pharmaceutical composition. See paragraph [0122] on page 12. Anti-emetics, such as granisetron and ondansetron, and an anti-diarrheal, such as acetorphan, may be combined. See

paragraphs [0046] and [0050], on page 3. Motivation to combine an anti-emetic and an anti-diarrheal is provided by Boige, a document that is drawn to digestive complications from cancer chemotherapy. See the discussions under **Prevention et traitement specifiques** and **Diarrhee**. Nausea, vomiting and diarrhea frequently occur following the administration of various cancer chemotherapeutic agents and regimens. Boige teaches an oral dosage of granisetron to be 1 mg every 12 hours, an oral dosage of ondansetron to be 8 mg every 8 hours and an intravenous dosage of ondansetron to be 32 mg. Additionally, dosages based on mg/kg body weight are provided. The specific enkephalinase inhibitor acetorphan, which is racecadotril, is specifically indicated in late-onset diarrhea.

Applicants argue racecadotril and ondansetron are listed in an extensive list of agents, and, in patients receiving chemotherapy, Boige describes ondansetron may be administered in the treatment of nausea while racecadotril may be administered for the treatment of diarrhea.

The Declaration provided by Dr. Lecomte is drawn to the co-administration of racecadotril and granisetron, wherein a side effect, the increase in the intestinal transit time induced by racecadotril, is suppressed. This showing is, however, not commensurate in scope with the present claims.

While Stroppolo lists categories of drugs, such as antidiarrheals and antiemetics, that may be combined in a formulation, Boige provides clear motivation to one skilled in the oncology art to select both an antidiarrheal and an anti-emetic for the specific patient population receiving cancer chemotherapeutic agents. According to Boige,

these patients frequently suffer gastrointestinal adverse effects from their chemotherapy and require therapy for nausea, vomiting and diarrhea. Thus combined therapy is clearly suggested.

The rejection of record of claims 1-19 under 35 U.S.C. 103 as being unpatentable over Stroppolo et al., US 2004/0115258, in view of Boige et al., Bulletin du Cancer, is maintained. Stroppolo teaches therapeutic formulations in which both an antidiarrheal and an anti-emetic may be combined, while Boige provides motivation to administer the specific antiemetic agents granisetron or ondansetron to treat nausea and vomiting, and the specific enkephalinase inhibitor acetorphan to treat diarrhea, in combination, following the administration of cancer chemotherapeutic agents.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 26, 2009

/Phyllis G. Spivack/

Primary Examiner, Art Unit 1614